

# Carrier Assembly Enables Single-Use Solution for BioPharma Needs

## Introduction

A leading global biopharmaceutical manufacturer had defined a strategic objective to launch a new product line centered on single-use technology developed in-house. The single-use technology involved a single-use bag with internal magnetic mixing technology designed for the life sciences market to reduce the manual labor required for mixing and to offer a single-use solution that would be cost-effective. To bring this solution to market, the bag and mixer, with their associated electrical drive assembly and electronic control cabinet, needed an appropriately designed and crafted carrier. This global company's development engineers teamed up with Terracon to fill this need and to design a complete solution leveraging their single-use mixing bags. The solution launched a line of single-use mixing systems.

## Challenge

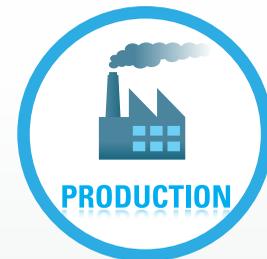
- **Sterility:** The end user needs to produce pharmaceutical ingredients from intermediate to final drug products and for the preparation of process solutions such as buffers and media in single-use bags validated to be clean and sterile.
- **Increasing efficiency and lowering costs –** The core challenge to be solved was reducing the downtime required for cleaning processes and the time invested in establishing and documenting validated cleaning processes that the FDA would accept as 100% reliable and repeatable. Terracon's customer identified a market opportunity to address this challenge, which had manufacturers making batches of product directly in expensive stainless-steel tanks and other vessels that required costly and elaborate cleaning processes.
- **The single-use bag was only half the solution.** Combined with Terracon's custom-designed carrier and assembly, a new product line was brought to market, and Terracon's customer delivered on its vision.

The customer sought to expand its product line to solve the above challenges in the life sciences sector. They turned to Terracon to design and produce the carrier assembly that would deliver a complete single-use solution for the biopharma market.

## Solution

A custom-designed carrier assembly comprised of:

1. Cylindrical Open-top Cone bottom (COC) tank with hinged door in tank sidewall
2. Custom fittings and features including flared legs for tip-over protection, and a base that includes fully locking casters for mobility, security, and stability.
3. Custom hinged access door whose form and location on the tank sidewall facilitates bag installation, visual confirmation of mixing activity, and access for product sampling devices.
4. Design of lower chassis enables simple disengagement of the motor from the mixing impeller for change-out, and guarantees that the motor assembly returns to the precise location to engage the magnetic impeller inside the single-use mixing bag.



*“The end solution, the single-use mixing systems, is a great example of the partnering approach that Terracon embraces in working with our customers’ engineers to design and fabricate a solution that suited their requirements while delivering an effective, efficient, and elegantly simple solution.”*

**Rob Jewett**  
PRESIDENT AND CEO  
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## Impact

- **Saved Time** – Involvement of Terracon's development team early in the process enabled the customer's design engineers to incorporate Terracon's years of plastic-working experience into their own product development process from the start.
- **Design Quality** – Throughout the iterative design process, no detail was considered carved in stone, because all relevant constituencies were represented in each discussion.
- **Effective Team Approach** – Ready availability of Terracon's team facilitated regular meetings, conversations, and experiments to keep the project rolling smoothly throughout the development process.

## Impact to End Users

- Reduce downtime for cleaning validation and process engineering.
- Achieves validation, quality, and regulatory compliance using single-use mixing bags with mixing impeller for 100% reliability and repeatability.
- Single-use technology promotes increased production capacity and decreased risk of contamination.
- Improved quality of mixing and production of drug product using the single-use bag and custom tank that are guaranteed to be clean and sterile.
- Easy to set up and transport; manual mobility of the vessel supports ease of use for the end user.
- The design of the tank solved a specific challenge of addressing the outlet hole and the filter housing to prevent bag extrusion.
- Design promotes ease of use by operator to properly align the bottom portion of the bag and to insert outlet tubing through the designated opening at the tank bottom.
- Closed, sterile sampling system enables representative samples.



## At Terracon, we solve the toughest fluid management challenges.

When it comes to challenges related to transferring, mixing or storing fluids we are your one-stop shop for integrated fluid management solutions.

If your requirements include repeatable cleanability, sanitary processing and/or high purity solutions, our team at Terracon can help. The more complex your need, the more we can help design and manufacture a solution that is cost effective and works.

## Terracon's Core Capabilities:

**Innovation & insight** – we creatively and costs effectively solve your fluid management challenges.

**Design expertise** – involve us early in the process to save you time and money. We focus on bringing new products to market to address the toughest challenges in fluid management.

**Engineering know-how** - our team is committed to creative solutions that meet your requirements and exceed expectations.

**Manufacturing** – from prototypes to production we offer full service solutions to get the job done well. We are the leading manufacturer for bringing to market “build to spec” and “build to application” plastic vessels and accessories.

**Terracon's fluid management solutions are distributed directly to OEMs via our sales team as well as through resellers and representatives.**

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